

REMARKS

Reconsideration of the above-identified application is respectfully requested. Claims 35, and 37-58 remain in the application.

Amendment of May 30, 2002

On May 30, 2002, Applicants filed a "Second Preliminary Amendment and Request Pursuant to 35 U.S.C. § 135 and 37 CFR § 1.607 That an Interference Be Declared" (Paper No. 36, dated in the Patent Office Database June 10, 2002). In that Amendment, Applicants set forth a set of claims, namely Claims 39-58, which they believe to be fully supportive by the present specification (see pages 5-7 of Paper No. 36). The "Second Preliminary Amendment" was filed almost 6 months prior to the mailing of the outstanding Office Action, yet was not referred to in that Office Action. Applicants would respectfully request that the Examiner consider Applicants' properly filed Second Preliminary Amendment. Applicants also request that the interference be declared.

Rejection Under 35 U.S.C. § 112, first paragraph

In the Office Action dated December 17, 2002, Claims 35-38 were rejected under 35 U.S.C. § 112, first paragraph, because the specification,

while being enabling for a therapeutic composition comprising 'early childhood' human annulus and/or nucleus intervertebral disc cells (if proper antecedent basis can be shown) and a carrier that contains any specifically fined and required cell stimulants/growth factors, does not reasonably provide enablement for such cells from adolescents or adult wherein annulus and/or nucleus cells no longer exist, or for compositions missing required/defined components. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims, for the reasons made of record in Paper Nos.: 3 and 7, etc. (*Office Action page 3*).

In rejecting the claims under 35 U.S.C. § 112, first paragraph, the Examiner also noted that the new claims again recited language similar to original Claims 10, 11, 13-15 and 17. As the Examiner will note, independent Claim 35 has been revised to clearly show that the claim is to a "method" of treating human disc disease. Thus, Claim 35 is now in the form of a method

claim as opposed to a "product by process" claim. Furthermore, the distinctions between the types of disc cells has been deleted.

Regarding Claim 37, the Examiner "notes that nowhere is there a requirement that 'the therapeutic compositions are secreting collagen'; only that a composition may contain collagen, etc., in which no other claims require such limitation." As noted, Claim 35 and, consequently, Claim 37, dependent thereon, have been amended to more clearly point out that they are "method claims" for treating human disc disease. To the extent that this rejection is understood, it is now believed to be moot in view of the amendments to Claim 35.

Applicants respectfully submit that with the amendments to Claim 35, the rejection under 35 U.S.C. § 112, first paragraph should be withdrawn.

Rejections Under 35 U.S.C. § 102(a)

Claims 35-38 stand rejected under 35 U.S.C. § 102(a) as being anticipated by Gruber *et al.* (Experimental Cell Research 235, 13-21 1997), and by Gruber *et al.* (Matrix Biology 16:285-288 (1997)).

In response to the rejection over the two Gruber *et al.* articles, Applicants submit herewith as Exhibit A, a "Declaration Pursuant to 37 C.F.R. § 1.132". As set forth therein, the Applicants, along with Mr. Fisher, Mr. Desai, Ms. Stasky and Ms. Hoelscher co-authored on the Experimental Cell Research Paper and in the case of Ms. Stasky, the Matrix Biology paper, co-authored the cited papers with the Applicants, all co-authors worked in the Applicants' laboratory under their supervision and direction while at the Carolinas Medical Center. The Applicants are the sole inventors of the invention described and claimed in the subject application. The remaining co-authors were named on the papers because of their work in Applicants' laboratory, but were not an inventor. The papers were published less than one year prior to the November 26, 1997 filing date of the subject application. Therefore, the Examiner is respectfully requested to withdraw his rejections in view of the "Declaration" (Exhibit A) and further in view of the holding of the former Count of Customs and Patent Appeals in *In re Katz*, 215 USPQ 14 (1992). A copy is enclosed as Exhibit B.

Lastly, Claims 35-38 were rejected under Chelberg *et al.* (J. Anat. 186:43-53 (1995)). The Examiner, in Paper No. 3, stated that "Chelberg *et al.* disclose a method of growing human

annulus and nucleus cells obtained from adult human intervertebral disc comprising isolating cells from the tissue, casting cells in alginate microspheres in the presence of a calcium chloride solution and incubating the cells in culture dishes in the presence of fetal bovine serum at 37°C further that the cells express a differentiated phenotype, *i.e.*, the cells synthesized glycosaminoglycans, Type I and Type II collagens, aggrecan, and other proteoglycans. As there is no distinction between the cells of Chelberg *et al.* and the cells of the instant invention, the reference of Chelberg *et al.* anticipates the claimed invention." In view of the amendments to Claim 35, it is respectfully submitted that Chelberg *et al.* does not in fact teach all of the steps of the claimed invention and therefore does not anticipate Claims 35 and 37-38.

In view of the arguments presented above, it is respectfully submitted that the claims as presented are allowable and that the interference should be declared.

It is not believed that extensions of time or fees for net addition of claims are required, beyond those that may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions of time are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 CFR § 1.136(a), and any fee required therefore (including fees for net addition of claims) is hereby authorized to be charged to Deposit Account No. 16-0605.

Respectfully submitted,

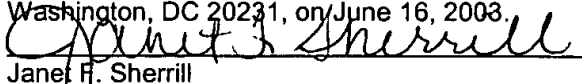


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CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, Washington, DC 20231, on June 16, 2003.



Janet F. Sherrill